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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,811	03/04/2002	Keizoh Kawaguchi	112137	1584

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EXAMINER

KIM, SUN U

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,811

Applicant(s)

KAWAGUCHI, KEIZOH

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,200,485 (hereinafter referred to as Kitaevich et al). Kitaevich et al teach a dialyzing apparatus comprising a dialyzer (24) which removes water from blood, blood pressure and heart rate monitors (120, 130) and other blood pressure change related information obtaining device obtaining systematic vascular resistance, cardiac output and hematocrit (110) and a controller (12) for gathering above blood pressure change related information independently or in combination with weight signals from infusate, drained fluid and patient weight and determining drained fluid rate based on above gathered data and changing water removal rate by manual or automatic mode to control flow rate of drain pump (66) i.e. dialyzer control device and display (13) for displaying measured data and computed parameters (see figure 2; col. 2, lines 59-62; col. 2, line 45 – col. 4, line 48; col. 5, lines 40-62; col. 7, lines 23-27; col. 7, line 63 – col. 9, line 47).

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,718,891 (hereinafter referred to as Lipps). Lipps teaches a dialyzing apparatus comprising a dialyzer (16) which removes water from blood, blood pressure change-related-information obtaining device such as heart rate monitor (12) and blood pressure monitor (14), a control device (10) i.e. water-remove-rate changing means controlling ultrafiltration rate i.e. water

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removal rate when blood pressure or heart rate deviates from the initial readings by more than preselected amounts (see col. 2, lines 28-66; col. 3, line 48 – col. 8, line 12).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitaevich et al as applied to claim 1 above, and further in view of European Patent Application No. 956815 (hereinafter referred to as EP '815). Kitaevich et al teach a dialyzing apparatus as described in above paragraph 2. Kitaevich et al teach that the monitored patient parameters include cardiac output, systemic vascular resistance and hematocrit (see abstract; col. 3, line 40 – col. 4, line 11) wherein a cardiac output reflects a blood flow parameter, systemic vascular resistance reflects a blood vessel parameter and hematocrit reflects a blood viscosity parameter. Claim 2 essentially differs from the apparatus of EP '815 in reciting an autonomic-nerve parameter that reflects an activity of an autonomic nerve of the patient. EP '815 teaches that the blood pressure is estimated by an expression (2) including pulse-wave propagation information and at least one of heart rate information and volume-pulse-wave area information wherein predetermined coefficients are changed by autonomic nerve activity determined by autonomic nerve system activity determining means (84) (see col. 11, line 3 – col. 15, line 2). It would have been obvious to a person of ordinary skill in the art to incorporate autonomic nerve system activity determining means of EP '815 in the apparatus of Kitaevich et al for improving the measurement of blood pressure. Regarding claim 4, EP '815 teaches that volume pulse wave

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such as photoelectric pulse wave is detected by detecting probe (38) (see figure 2; col. 7, line 47 – col. 8, line 54) and circulation information means (72) includes at least one of heart rate information obtaining means (74) and a volume-pulse-wave area information obtaining means (76) (see figure 2; col. 10, line 19 – col. 11, line 2). Regarding claim 5, EP '815 teaches that the autonomic-nerve parameter includes an activity of a sympathetic nerve system based on a low-frequency component and an activity of a parasympathetic nerve system based on a high-frequency component of the fluctuations of the blood pressure (see col. 12, line 56 – col. 15, line 3) and a ratio of amplitude of the high-frequency component to an amplitude of the low frequency component (see col. 19, line 11 – col. 21, line 6). Regarding claim 6, EP '815 teaches a pulse wave propagation information obtaining means (70) which obtains pulse-wave propagation velocity and pulse-wave propagation time (see col. 9, line 43 – col. 10, line 18). Regarding claim 7, Kitaevich et al teach a hematocrit sensor (110) (see figure 2).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

A handwritten signature in black ink, appearing to read "John Kim".

John Kim
Primary Examiner
Art Unit 1723

J. Kim
July 15, 2003